REMARKS

Examiner Interview

Applicant thanks Examiner Campbell and Examiner Lucchesi for the helpful telephonic interview on November 13, 2008 with the undersigned and Attorney James Smith. During the Interview, it was agreed that Claim 24 would be amended to incorporate the "prior to any injection" limitation presented in different terms in claim 27 to further distinguish from the primary reference, Hagen (U.S. 5,354,273). Accordingly, Claim 24 now corresponds in scope to prior independent claim 30. A formal interview summary is also being filed herein.

102(b) Rejections

Claim 27 has been rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,354,273 to Hagen. Claim 27, and dependent claims 28-30, have been cancelled and thus this rejection no longer applies. Application reserves the right to refile Claim 27 and dependent Claims 28-30 in a continuation application.

103(a) Rejections

The Examiner has rejected claims 24-26 and 28-30 (now cancelled) under 35 U.S.C. 103(a) as being unpatentable over Hagen in view of U.S. Patent 6,132,385 to Vain.

An embodiment of Applicant's device will be discussed without limitation of the claims. As shown in Applicant's Figure 13, there is shown a skin property sensor 200 associated with the drug delivery device 10. The sensor 200 can be integrated with the device 10, or it can be a separate unit. As shown, the sensor is positioned within the device 10, with the sensor tip 201 located near the orifice 14 of the injector.

When the device 10 is used with the sensor 200, the device 10 is initially placed against the skin S, of the body such that the sensor tip 201 also rests against the skin. The controller 50 then drives the voice coil 202 to perturb the skin, while the force transducer 202 detects the force that the tip 201 applies to the skin, and the LVDT 208 detects the displacement of the skin prior to any injection.

The controller drives the source probe using a stochastic sequence. The data received from the sensor is fed back to the controller 50 which then evaluates the skin properties with the system identification techniques. Based on the detected skin properties, the controller 50 directs the actuator 28 to eject the drug, D, contained in the chamber 12, through the orifice 14 with the desired injection pressure based on the initially determined properties.

Hagen describes a delivery apparatus for delivery of various media. As shown in Hagen's Figure 1, actuating power for the device is supported by the high pressure gas supply 30 to supply actuating gas under controlled pressure through a precision pressure regulator 34. The pressure of the actuating gas is controlled by a pressure setting control 26. The device also includes a compartment and piston apparatus 40, and actuating rod 52. The piston is further connected to the delivery apparatus 12 containing fluid 14. The pressure on the piston is regulated by comparing the actual pressure applied to the piston versus the pressure setting. The difference is the error and is reduced to zero to keep the pressure at the set level.

The device can have a pressure and/or temperature sensing element 27 to sense the pressure level of the medium being dispensed at the point where it is actually delivered for use, and/or to sense the skin temperature of the patient during the injection. The pressure setting can then be adjusted based on the pressure at the delivery point. The skin temperature of the patient can also be used as a parameter to sense if the pressure setting needs adjusting or shutting down (Col. 6, lines 58-68).

As shown in Vain's Figure 2, Vain describes a device for recording the oscillations of soft biological tissue. An investigator places a testing end 6 on a joining marker 12, previously attached to biological tissue by means of an adhesive, vacuum, or some other mechanical coupling. An electrical current is switched on to a solenoid 8 for a previously fixed time period and during this time period an armature 9 is pulled into the solenoid 8 by its electromagnetic field; as a result, the testing end exerts to the tissue under investigation a mechanical impact through the joining marker. When the testing is complete, the biological tissue together with the joining marker and testing end perform damping oscillations, the characteristics of which are dependent on the elasticity and mechanical properties of the soft biological tissue under investigation.

The Examiner acknowledges that Hagen fails to teach that the skin measurement taken is the displacement of the skin after an applied force. She, however, states that it would have been obvious for one to modify the measuring device of Hagen to include the source probe (testing end 6) and driver of Vain because doing so would offer a more complete description of the skin's properties than just taking surface temperatures. Applicant respectfully disagrees.

Firstly, one would not look to combine the device of Hagen and Vain, as they are completely distinct devices with different functions. Hagen's device is a needle-free injector which senses temperature of the skin and pressure of the dispensed medicine in order to adjust the pressure of the dispersed medicine during the injection based on these factors. Vain's device is a diagnostic one for recording mechanical oscillations in soft biological tissue for the purpose of monitoring tissue properties in response to various processes, such as the efficiency of massage procedures, surgical operations, physiotherapeutic procedure, rehabilitation gymnastics, and drug treatment (Cain, Col. 1, lines 1-17 and lines 56-62). There is no suggestion that the measurements be associated with an injection.

Hagen nowhere suggests a need for measuring any properties of the skin other than temperature. Additionally, Vain nowhere describes or suggests use of his device as relating to injection into the skin. Thus, one would have no reason to combine Hagen's injector with Vain's device. Even if one were to seek additional properties for Hagen's sensor to sense, one would look towards other injectors, not Vain's diagnostic method.

Even if one did combine them, neither Hagen nor Vain either alone or in combination describe the limitation of prior to any injection, adjusting the injection pressure of the injector with a servo-controller based on displacement as is recited in amended claim 24. Hagen describes adjusting the temperature during the injection, not prior to it. Thus, Hagen controls based on responses to the injection; whereas Applicant pretests the skin to predetermine an appropriate injection pressure. As stated, Vain does not describe an injection at all. Thus, claim 24 or any claim dependent on the same is allowable for at least these reasons.

Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement (SIDS) was filed on September 17, 2008. Entry of the SIDS is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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